

REMARKS

Upon entry of the following amendments, claims 1-34 constitute the pending claims in the present application. No claims are cancelled or objected. Claims 6, 8, and 18-30 are withdrawn. Claims 1-5, 7, 9-17 stand rejected. Claims 31-34 are new.

Claim Amendments

To more particularly define the claimed invention, Applicants amend claims 1 and 15-17 to recite that the “linking molecules crosslink the polymer through inclusion complexes.” Support for these amendments can be found throughout the specification including page 4, lines 14-22, page 5, line 1-4, and page 32, line 20-21, and Example 19. Applicants assert these amendments present no new matter.

New Claims

New claims 31-33 find support throughout the application as originally filed. For example, support for claims 31-32 can be found on page 5, lines 1-10, page 32, lines 16-28, and in Fig. 2 and the corresponding passages in the specification. Support for claim 33 can be found at least in the first paragraph on page 6, lines 1-10. Furthermore, the synthesis of several linking molecules as distinct species are described in the Exemplification section of the original specification, such as in Examples 7, 11, 12, and 14, and additional support can be found in Figs. 1-2. Support for claim 34 can be found throughout the specification including page 4, lines 14-22, page 5, line 1-4, and page 32, line 20-21, and Example 19. Applicants assert new claims 31-34 do not constitute new matter.

Applicants respectfully request reconsideration in view of the following remarks. Issues raised by the Office will be addressed below in the order they appear in the prior Office Action.

Restriction Requirement

Applicants appreciate the clarification provided by the Office regarding the issues in the outstanding Restriction Requirement. While Applicants do not necessarily agree with the Office’s findings, Applicants acknowledge finality of outstanding restriction requirement and that claims 6, 8, and 18-30 are withdrawn. Applicants again highlight that pursuant to 37 CFR 1.141 and MPEP 809 and 821.04, on a finding of allowability of a generic product claim, for example, claim 1,

rejoinder and consideration of any additional species which depend from or otherwise require all the elements of the generic product claim, for example, claims to processes for making or using the product, are required as a matter of right.

Claim Rejections – 35 U.S.C. 112, 2nd paragraph

Claims 2-5, 7 and 9-14 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicants regard as the invention.

The Office contends that “there is insufficient antecedent basis” for the limitation “A polymer.” The Office asserts that dependent claims “2-5, 7, and 9-14 should be prefaced by ‘The polymer’ in each claim to provide proper antecedent basis.”

While Applicants do not necessarily agree with the Office’s position, especially in light of the fact that the Office does not cite nor are Applicants aware of any portions from the CFR or the MPEP that specifically supports the rejection, in order to advance prosecution, Applicants amend claims 2-5, 7, and 9-14 to recite “The” instead of “A.”

Claim Rejections – 35 U.S.C. 103(a)

Claims 1 and 15-17 are rejected under 35 U.S.C. 103(a) as being unpatentable over Middleton et al. Synthetic biodegradable polymers as orthopedic devices, Biomaterials 21 (2000), pgs. 2335-2346 (“Middleton”) and USPGPUB 2001/0034333 A1 (“Kosak”). The Office states that Middleton teaches the “practicing art of polymer biopharmaceuticals,” “biocompatibility and biodegradability [sic] and all characterizations and susceptibilities of such above properties” (See page 7 of the outstanding Office Action). The Office states that Kosak “teaches compositions of cyclodextrin polymers for carrying drugs and other active agents,” “compositions... of cyclodextrin polymer carriers that release drugs under controlled conditions,” and “compositions of cyclodextrin polymer carriers that are coupled to biorecognition molecules for targeting the delivery of drugs to their site of action.” *Id.* The Office further states that Kosak teaches “inclusion complex formation and dissociation,” “inclusion complex with a cyclodextrin or cyclodextrin polymer,” “cyclodextrin functioning as a ‘host’ molecule, combined with one or more ‘guest’ molecules that are contained or

bound, wholly or partially within cavity,” “a practicing method linking molecules linking to the polymer crosslinking [sic]” (although it is not clear what is meant by this statement), and “cyclodextrin polymer bonds to polymer backbone.” *Id.* at 7-8. The Office asserts that it is “*prima facie* obvious to combine two compositions each of which is taught by the prior art to be useful for the same purpose.” The Office additionally states that “one of ordinary skill in the pertinent art of polymer biopharmaceutics at the time of the invention would have at once recognized a reasonable expectation of success by incorporating the teachings of Middleton et al. and Kosak,” and that “Kosak teaches the motivation to combine.”

Pursuant to MPEP 2142, “[t]o establish a *prima facie* case of obviousness ... the prior art reference (or references when combined) must teach or suggest all the claim limitations.” *In re Vaeck*, 947 F.2d 488, 20 USPQ2d 1438 (Fed. Cir. 1991). Applicants assert that the Office has not satisfied this requirement. In particular, claims 1 and 15 of the instant application recite a polymer composition comprising “... linking molecules, each linking molecule comprising at least two moieties that form inclusion complexes with the inclusion hosts, wherein the linking molecules crosslink the polymer through inclusion complexes.” Claim 16 of the instant application recites a polymer composition comprising “... linking molecules, each linking molecule comprising at least three moieties that form inclusion complexes with the inclusion hosts, wherein the linking molecules crosslink the polymer through inclusion complexes.” The Office has not indicated any passages in Kosak that teach or suggest linking molecules as defined in the instant claims. For example, the Office has not indicated where Kosak teaches or suggests linking molecules that comprise “at least two moieties” (claims 1 and 15) or “at least three moieties” (claim 16), let alone linking molecules whose moieties “form inclusion complexes with inclusion hosts” (claims 1, 15, and 16) or even linking molecules that “crosslink the polymer through inclusion complexes” (claims 1, 15, and 16 as amended). The Office cites paragraphs [0082] and [0091] of Kosak, but these sections teach “covalent cross-link bonds” and “a biocleavable cross-linking agent,” respectively. They do not teach linking molecules with the structural features and properties recited in the instant claims.

Claim 17 of the instant application recites a polymer composition comprising "... linking molecules, each linking molecule comprising at least two moieties that form inclusion complexes with the cyclodextrin moieties, wherein each cyclodextrin moiety has no more than two bonds to the polymer backbone, and the linking molecules crosslink the polymer through inclusion complexes." Kosak does not teach or suggest linking molecules that form inclusion complexes with cyclodextrin moieties. Furthermore, as stated above, Kosak does not teach or suggest linking molecules comprising at least two moieties that form inclusion complexes generally. Nor does Kosak teach linking molecules that crosslink the polymer through inclusion complexes. As such, the Office has not demonstrated that Kosak teaches or suggests these several features of claim 17.

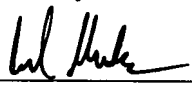
For the above reasons, Applicants assert that Middleton and Kosak, either alone or in combination, fail to teach or suggest all the features of present claims 1 and 15-17, and thus these references cannot properly form the basis for the present obviousness rejection. Consequently, Applicants request reconsideration and withdrawal of the rejection over these references.

CONCLUSION

Applicants believe no fee is due with this response. However, if a fee is due, please charge our Deposit Account No. 18-1945, under Order No. ITI-P01-010 from which the undersigned is authorized to draw.

Dated: September 28, 2007

Respectfully submitted,

By 

Carl A. Morales, Ph.D.
Registration No.: 57,415
ROPES & GRAY LLP
One International Place
Boston, Massachusetts 02110
(617) 951-7000
(617) 951-7050 (Fax)
Attorneys/Agents For Applicant